REMARKS

Reconsideration and allowance of the subject application are respectfully solicited.

Claims 16-33, 35, 37-45, 47 and 49-66 are currently pending in this application, with Claims 16, 33, 45 and 53 being independent. Claims 16-33, 35, 37-44, and 62-64 have been withdrawn from consideration. Applicant submits that no new matter has been added.

By a Request for Reconsideration and Contingent Petition for Withdrawal of Restriction Requirement filed concurrently herewith, Applicant requests that the Examiner reconsider and withdraw the restriction requirement that was made final in the above-noted Office Action.

In the Official Action, the specification has been objected to because the sequences set forth on pages 4-6 of the specification were allegedly not included in the required CRF and paper copy, in violation of 37 C.F.R. §§ 1.821-1.825. Applicant directs the Examiner's attention to the CRF and paper copy filed on August 9, 2004. Applicant submits that the CRF and paper copy fully comply with 37 C.F.R. §§ 1.821-1.825. Applicant requests reconsideration and withdrawal of the objection.

The specification was objected to for failing to append SEQ ID Nos. to all mentions of specific sequences in the specification. Applicant directs the Examiner's attention to the Preliminary Amendment filed on September 11, 2003, and submits that the Preliminary Amendment appended SEQ ID Nos. to all mentions of specific sequences in the specification. Applicant requests reconsideration and withdrawal of the objection.

The specification was objected to for numerous informalities. Applicant submits that the informalities were corrected by the amendments made herein and by the amendments made in the Preliminary Amendment filed on September 11, 2003. Reconsideration and withdrawal of the objection are requested.

Claims 45, 47, 49-61, 65 and 66 have been objected to for containing non-elected subject matter. Applicant submits that the objection to Claims 49-52, 65 and 66 is misplaced because those claims all require the presence of the elected SEQ ID NO. 18. Reconsideration and withdrawal of the objection to Claims 46-52, 65 and 66 are requested. Additionally, in light of the concurrently filed Request for Reconsideration and Contingent Petition for Withdrawal of Restriction Requirement, Claims 45, 47 and 53-61 have not been amended. If the Request for Reconsideration and Petition are denied, Applicant will address Claims 45, 47 and 53-61 at that time. Applicant, therefore, requests that the objection be held in abeyance until that time.

Claims 53-61, 65 and 66 have been rejected to under 35 U.S.C. § 112, first paragraph, for lack of enablement. This rejection is traversed.

Applicant's invention, as recited in independent Claim 53 is directed to a pharmaceutical composition for stimulating the immune system of a human to produce an HIV-1 immune response. The Examiner has taken the position that Claim 53, when read in light of the specification, is really intended to be equivalent to a vaccine for preventing or treating HIV-1 infection. The Examiner asserts that one of ordinary skill in the art could not practice the full scope of the Claim 53 without undue experimentation. Applicant respectfully disagrees.

Applicant initially notes that pursuant to MPEP § 2111.01 the words of a claim are to be given their plain meaning unless applicants have provided a clear definition in the specification. Applicant submits that the phrase "pharmaceutical composition for stimulating the immune system of a human to produce an HIV-1 immune response" has not been specifically defined to mean "a vaccine for preventing or treating HIV-1 infection." Applicant further submits that the Claims 53-61, 65 and 66 have been enabled to allow one of ordinary skill in the art to practice the full scope of these claims. Applicant notes that the composition according to Claim 53 comprises four peptides, one of which is selected from the group consisting of SEQ ID NOS 16-20. The peptides of SEQ ID NOS 16-20 are derived from generic SEQ ID NO 15, which concerns peptides developed from the natural sequence 166-186 of the Los Alamos sequence (i.e., the sequence listed on page 6 of the specification). SEQ ID NOS 16-20 contain a common modification, as compared to the native equivalent sequence, in a $[Gly]_n[Arg]_m$ linker, where n=1, 2 or 3 and m=0, 1, 2, or 3 inserted between position 176 and 177. In SEQ ID NO. 18, n=2 and m=2. Applicant also notes that preparation of these peptides is set forth in Example 11 on page 18 of the specification.

Further, Applicant directs the Examiner's attention to the Declaration of Dr. Ingebjørg Baksaas and the Exhibits A and B attached thereto that were submitted on August 3, 2005. (For the Examiner's convenience, a copy of the Declaration and Exhibits is attached hereto.) Exhibit A relates to a clinical phase II trial including the composition of Example 14 and Claim 66, i.e., a composition including the peptides of SEQ ID NOS 3, 6, 11 and 18 (designated "vacc-4x" throughout Exhibits A and B) and describes delayed type hypersensitivity (DTH) tests of the composition and of each of the four peptides alone.

As can be seen from Exhibit A, the median values for the peptide of SEQ ID NO 18 show that this peptide is immunogenic (*see* Exhibit A, Figure 1). T-cell proliferation responses show that the peptide of SEQ ID NO 18 gives a very strong response when compared with a native HIV-1 clade B p24 peptide (*see* Exhibit A, Figure 2).

Exhibit B describes the same clinical phase II study as Exhibit A and presents data on CD4+ T-lymphocyte counts, DTH tests and analysis of T-cell proliferation measured in peripheral blood mononuclear cells (PBMC). The open prospective randomized phase II clinical study, which included 38 healthy HIV positive patients stable on antiretrovial therapy (HAART), resulted in a finding that patients remained HAART-free for a median of 70 weeks after immunization with the vacc-4x composition. The group receiving immunizations with the vacc-4x composition (described in Example 14 and Claim 66 of the subject application) showed a significantly lower decline in mean CD4+ T-cell counts ($p=0.0005$) and a small but significant delay in viral rebound ($p=0.02$). The patients receiving immunizations with the vacc-4x composition stayed off HAART significantly longer than the Athena patients (patients that interrupted HAART without receiving the vacc-4x composition) (*see* Exhibit B, page 2). That is the patients receiving the vacc-4x composition stayed off HAART for 70 weeks while the Athena patients stayed off HAART for 17 weeks (*see* Exhibit B, Figures 9 and 10).

Applicant submits that Exhibit B also provides data showing that all of the peptides of the vacc-4x composition (SEQ ID NOS 3, 6, 11 and 18) contribute to the immunogenic effect thereof (*see* Exhibit B, Figures 2 and 4). Applicant also submits that figures 5 and 6 of Exhibit B further indicate that immunization with the vacc-4x composition involve cross-reactions increasing the proliferation response to HIV-1 p24

(*see* Exhibit B, page 6) and that responsiveness to the vacc-4x composition is associated with improved viral control.

Finally, Applicant notes that, for example, U.S. Patent Nos. 6,723,558 B1 and 6,787,351 B2 recite claims directed to HIV vaccines and that those patents do not provide human test data indicating that the vaccines are effective for that purpose. That is, these patents were granted based on a standard of enablement that differs from the standard apparently required by the Examiner. Applicant submits that the subject application, in view of the Declaration of Dr. Baksaas, recites as much or more proof of the effectiveness of the compositions of Claims 53-61, 65 and 66 than do the above-listed patents.

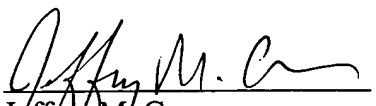
In view of the foregoing, Applicant submits that the full scope of the subject matter recited in Claims 53-61, 65 and 66 has been enabled and that one of ordinary skill in the art is able to practice the full scope of the claims without undue experimentation. Reconsideration and withdrawal of the § 112, first paragraph, rejection are requested.

Applicant submits that the present invention is patentably defined by independent Claims 16, 33, 45 and 53. Dependent Claims 17-32, 35, 37-44, 47, 49-52 and 54-66 are also patentable, in their own right, for defining features of the present invention in addition to those recited in the independent claims. Individual consideration of the dependent claims is requested.

Applicant submits that the present application is in condition for allownace. Reconsideration, withdrawal of the restriction requirement, objections and rejections indicated the above-mentioned Office Action, and an early Notice of Allowance are requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 530-1010. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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